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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,955	01/15/2002	Michael S. Roberts	2370-84	5046

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NIXON & VANDERHYE, PC  
901 NORTH GLEBE ROAD, 11TH FLOOR  
ARLINGTON, VA 22203

EXAMINER

BROWN, TIMOTHY M

ART UNIT PAPER NUMBER

1648

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/044,955

Applicant(s)

ROBERTS ET AL.

Examiner

Timothy M. Brown

Art Unit

1648

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 31 May 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-127 is/are pending in the application.
- 4a) Of the above claim(s) 1-77 and 81-127 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 78 is/are rejected.
- 7) ☒ Claim(s) 79 and 80 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f):
- a) ☐ All   b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### DETAILED ACTION

This Non-Final Office Action is responsive to the communication received May 31, 2005.

Claims 1-77 and 81-127 are withdrawn from consideration. Claims 78-80 are under examination.

#### *Claim Objections*

Claims 79 and 80 are objected to for depending from a rejected independent claim.

Amending the claims to incorporate all the limitations of independent claim 78 would overcome this rejection.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

***Claim 78 is rejected under 35 U.S.C. 103(a) as being unpatentable over Martuza et al. (US 5,278,379) in view of McCormick (US 5,677,178).***

Applicants claim a method for identifying a virus likely to have antineoplastic activity in a mammal comprising exposing a candidate virus to (i) cells deficient in an interferon-mediated antiviral activity, and (ii) cells competent in said interferon-mediated antiviral activity, and

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determining whether the amount of virus required to said deficient cells is at least 5 times less than the amount of virus required to kill said competent cells. Determining that at least 5 times less virus is required to kill said deficient cells provides an indication that said virus is likely to have antineoplastic activity in a mammal.

Martuza et al. disclose a screening method for identifying antineoplastic viruses comprising contacting a recombinant herpes simplex virus (HSV) with a population of tumor cells, and comparing the ability of the virus to replicate in the tumor cells with the ability of the virus to replicate in a population of non-tumor cells, wherein the tumor cell population may comprise HepG2 cells, breast carcinoma cells, or SW480 colon cells (col. 20, lines 12-27). Martuza et al. do not expressly disclose that its tumor cell population is deficient in interferon-mediated antiviral activity. However, Applicants' specification teaches that HepG2 cells, breast carcinoma cells, and SW480 cells are deficient in interferon-mediated antiviral activity (see e.g. pp. 9 and 32). Thus, Martuza et al. meets the claimed interferon-mediated antiviral activity through inherency.

Martuza et al. do not expressly disclose determining whether the amount of virus required to kill the cells deficient in interferon-mediated antiviral activity is five times less than the amount required to kill the cells competent cells in the interferon-mediated antiviral activity. However, McCormick teaches measuring the ability of a virus to preferentially infect tumor cells by comparing the multiplicity of infection (MOI) required to kill tumor cells, versus the MOI required to kill non-tumor cells (col. 20, lines 6-29). One skilled in the art would have appreciated that Martuza et al.'s use of plaquing assays as a measure of oncolysis (col. 20, lines 21-25) could have easily been carried using McCormick's MOI assay. Measuring viral lysis is a matter of routine experimentation and a skilled artisan's use of plaquing assays or MOI is simply a matter of choice. One skilled in the art could therefore reasonably expect McCormick's assay to provide a measure of oncolysis. Moreover,

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Applicants' use of MOI would not produce an unexpected result since it simply provides a measure of a virus' ability to replicate. Thus, at the time of Applicants' invention, it would have been obvious to one of ordinary skill in the art to substitute Martuza et al.'s plaquing assay for McCormick's use of MOI as a measure of oncolysis.

***Response to Arguments***

Claims 78-80 were rejected for failing to comply with the enablement and written description provisions of 35 U.S.C. 112, first paragraph. These rejections have been withdrawn in view of Applicants' amendment. Claims 78-80 were rejected for failing to comply with 35 U.S.C. 112, second paragraph. This rejection has been withdrawn in view of Applicants' remarks and amendment.

***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure:

- i) Duncan, M.R. "Differential Sensitivity of Normal and Transformed Human Cells to Reovirus Infection" J. Virol. (1978) 28, 2, 444-449)
- ii) Martuza et al. (US 5,585,096) Replication-competent herpes simplex virus mediates destruction of neoplastic cells; see col. 16, line 55 through col. 17, line 36)

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Timothy M. Brown whose telephone number is (571) 272-0773. The examiner can normally be reached on Monday - Friday, 8am - 5pm.


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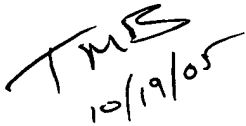
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel can be reached on (571) 272-0902. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Timothy M. Brown  
Examiner  
Art Unit 1648

tmb

  
JAMES HOUSEL 10/31/05  
SUPERVISORY PATENT EXAMINER  
TECHNOLOGY CENTER 1600

  
TMB  
10/19/05